Expansion of a Pharmacist's Role in a Pediatric Ambulatory Clinic Setting at a Large Academic Medical Center

by

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Abstract:

Expansion of a Pharmacist's Role in a Pediatric Ambulatory Clinic Setting at a Large Academic Children's Medical Center

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Background: Texas Children's Hospital (TCH) is a 658-bed pediatric hospital consisting of 45 ambulatory care clinics that receive 21,990 patient visits per month. The TCH infusion center administers roughly 900 high-risk medications per month for patients seen in endocrinology, allergy & immunology, GI & hepatology, and pulmonary clinics. Patients are scheduled for an appointment to the infusion center and their medication infusion plans are entered in advance by prescribers. Upon the day of patient appointment, orders from infusion plans are "released" by nursing staff for pharmacy verification and preparation. I would add more of a description that reveals that there is no real monitoring or pro-active review rather than the steps in patient appointments. Also add a hint of what is to come- the need for review prior to administration.

Objectives: The primary objectives of this study are: 1) Develop specific monitoring parameters for high-risk medications commonly used in the infusion center 2) Create and implement a tool to evaluate appropriateness of orders (laboratory monitoring, dose, duration of therapy, post-infusion monitoring) 3) Identify financial risk and benefit for the organization through increased pharmacy presence in a high-risk, high-cost ambulatory setting servicing special populations.

Methods: This is a single institution, retrospective analysis of pediatric patients 2 to 18 years of age treated at Texas Children's Hospital Outpatient Infusion Center between September 15, 2013 and February 7, 2014. Patients were included if they received one of the following 5 identified high-risk medications in the infusion center: methylprednisolone, infliximab, immune globulin, methotrexate, omalizumab. Exclusions included patients > 18years of age and those not receiving any of the specific monitoring parameters for the selected drugs were developed. Additionally, 4-day pre-screenings of patients scheduled for appointments from January 6, 2014 through February 7, 2014 were performed by a clinic pharmacist. Therapy plans entered by physicians for patients in the EHR were utilized by

the clinic-based pharmacist to prospectively review medications and make appropriate interventions. Data collection included the following parameters for high risk medications:

- medication-specific monitoring labs
- pre-medications
- dosage
- duration of therapy
- post-infusion monitoring.

Potential adverse drug events were collected from retrospective and prospective chart review. Data were collected on paper forms and results were transcribed into an electronic database. Estimated cost avoidance (ECA) of identified potential adverse events was quantified using methods from existing literature

Results: Standard monitoring parameters for the following five drugs were developed: methylprednisolone, infliximab, immune globulin, methotrexate, omalizumab. Therapy plans entered by physicians for patients in the EHR were utilized by the clinic-based pharmacist to prospectively review medications and make appropriate interventions. Twenty-six interventions out of 206 total orders were made during a 1-month period. A retrospective review of 569 orders over a 3-month period revealed 55 inappropriate orders. Number of adverse drug events (ADE) found during the 1-month prospective review broken down by ADE category: labs – 12, dosage – 2, duration – 3, adverse drug reaction – 3, documentation – 6. A 1-month estimated cost avoidance of $3,164 was realized, extrapolated to $37,968 per year.

Conclusions: Implementation of a pharmacist performing prospective reviews of patients scheduled for appointment in the infusion center using developed monitoring parameters contributed to estimated cost avoidance for the health system. Medical and pharmacy staffs were receptive of pharmacist's prospective review and were actively engaged in reviewing changes based on interventions Tools utilized to perform this function will be further developed for future use through expansion of standardized monitoring parameters for other commonly infused medications and more seamless communication to providers about interventions.

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Background

Ambulatory services provided by large healthcare systems continue to expand in scope and volume, as health care systems are being impacted by coverage, reimbursement and quality initiatives while also contributing to higher quality and lower costs[1-4]. Furthermore, there has been extensive evidence that pharmacists can have a positive impact on patient outcomes in the ambulatory clinic setting[5]. The pharmacist's role in these clinics has involved focusing on adherence, clinical consultation, prospective review, and prescribing[6-10]. Much of the research has focused on the adult population and the management of chronic disease states such as heart failure, diabetes, cholesterol and others[11].

One publication described the methods for implementing dialysis pharmacy services, complying with prospective order review after initiating services through audits of patient visits, and providing clinical interventions by pharmacists. Over a four-month period, pharmacists documented a total of 77 clinical interventions with a 100% acceptance rate by physicians. Of the total interventions, 11 were therapeutic related, 49 were safety related, and 17 were compliance related. The authors concluded that implementing a prospective pharmacy review in a dialysis unit reiterated the positive impact pharmacists can have in guiding treatment regimens in patients with chronic kidney disease[7].

In the pediatric setting, research studying pharmacist's impact in ambulatory clinics has not been as extensive. One study evaluated the impact of a pharmaceutical care program administered by a pharmacist to children with asthma. A comprehensive asthma education and monitoring program that includes basic asthma knowledge, symptoms and exacerbation evaluation, pharmacotherapy assessment including inhaler technique, and quality of life measurements was developed. All patients with moderate asthma scheduled for outpatient visits with their internist over a 1-year period were referred for pharmacist intervention. Patients (aged 7-17) with moderate asthma attending the clinic were allocated to the intervention (group A) or control group (group B). Intervention patients (group A) were educated on their disease, pharmacotherapy, self-management, and inhalation techniques. Group B consisted of children with their regular treatment for asthma but without pharmaceutical intervention. A pediatric asthma quality of life questionnaire (PAQLQ) was applied to both groups at 0, 2, and 9 weeks to assess the quality of life, with spirometry testing being done at the beginning and at the completion of the 9-week study. For the individual domains of activities, emotions, and

symptoms there was a significant improvement in the children who received pharmaceutical care in comparison with those who did not receive it. The scores of group B did not change during the 9 weeks of follow-up with no significant changes in spirometric values in either group[12].

Another study conducted by So and colleagues focused on identifying the potential roles of a clinical pharmacist as a provider in a pediatric nephrology and hypertension clinic. Patients ≤18 years of age taking at least one medication were consecutively enrolled in the study, with demographic information and interventions performed during the clinic visit by a clinical pharmacist being recorded. Three hundred and seventy-four visits made in 283 participants were evaluated. Types of cognitive pharmacy interventions included medication counseling, verification of current medications, medication adherence, amongst others. The mean (SD) number of cognitive pharmacy interventions per patient was 2.3 (1.0) on the first visit, with the mean (SD) number of medications per patient being 5.7 (4.8) and of medications counseled per visit was 4.0 (3.4). Medication adherence was investigated in 141 (38%) visits. Discrepancies of medications were discovered in 12 of the 374 visits. The authors concluded based on the results that pediatric cognitive pharmacy services delivered to patients in a pediatric nephrology clinic were feasible and improved the quality of services while also promoting better outcomes for patients[13].

Texas Children's hospital is a 582-bed academic medical center with approximately 45 ambulatory clinics attached to the hospital. In 2012, the hospital averaged 21,990 ambulatory clinic visits per month. One of these is a nursing-run clinic that serves as an infusion center for patients to receive non-oncologic intravenous medications. The infusion center accommodates roughly 400 appointments per month, with ~900 medications infused during that time. Patients seen in allergy & immunology, gastrointestinal, life-threatening asthma, and endocrinology clinics make appointments for the infusion of medications to treat chronic diseases. As the function of the infusion center is to administer medications, there is a limited physician presence in the clinic. Orders for patients are entered by physicians in advance of the appointment via "therapy plans." These therapy plans outline all aspects of the infusion center visit, from labs to be drawn, hydration parameters, dose, infusion duration, post-infusion monitoring, and interval of appointments. Upon the patient arriving to clinic, these pre-entered therapy plan orders are "released" by nursing staff, which are then verified and prepared in the ambulatory care pharmacy satellite. As patient-specific therapy plans are viewable by

all health-care staff with the exception of pharmacy, the current structure does not lend itself to a true prospective review of orders. The pharmacist will not see the medication plan for the appointment, only the actual medication orders once they are released. As there are many other considerations for the safe use of high-risk medications besides right drug, right dose, and right durations, the pharmacist not having access to information such as pre-labs, frequency, and previous medical history in one place is a barrier to care. Patients travel from long distances to receive their infusions, and since the orders cannot be released until they have been checked in, the patient sits in the infusion chair for many hours while the medication is prepared by pharmacy. This leads to a perceived delay in service and thus potentially impacts patient and nursing satisfaction adversely. Furthermore, due to the high risk nature of many of the medications, a true prospective review by a pharmacist that allows for examination of all aspects of the therapy plan would possibly have an impact on increased patient safety within the infusion center.

The primary objectives of this study were to address this gap in patient safety by developing specific monitoring parameters for high-risk medications commonly used in the infusion center, creating and implementing a tool to evaluate appropriateness of orders (laboratory monitoring, dose, duration of therapy, post-infusion monitoring), and identifying financial risk and benefit for the organization through increased pharmacy presence in a high-risk, high-cost ambulatory setting.

Methods

To identify medications for which specific monitoring parameters should be developed, a year-long report of medications used in the infusion center was analyzed along with the presence of FDA boxed warnings. An interdisciplinary team including clinical pharmacy specialists, ambulatory center staff pharmacists, infusion center nursing coordinators, and infusion center nursing staff targeted the following parameters for identified high-risk medications: labs, dose, indication, duration of therapy, post-infusion monitoring. Medication package inserts, TCH formulary, existing literature, and primary anecdotal evidece were utilized in the development of monitoring parameters for each medication. For the purposes of the study, five medications were chosen.

In order to establish a standardized prospective review of patients, pre-screenings of patients one week prior to scheduled appointments from January 6, 2014 through February 7, 2014 were performed by a clinic pharmacist stationed within the infusion center.

With the intention of establishing a baseline for comparison of pre- and post-prospective review data, a retrospective chart review was performed for patients receiving any of the five identified medications from September 15, 2013 through December 15, 2013 to determine appropriateness of the order. Interventions made by the clinic pharmacist were logged and classified into the following categories: labs, dosage, duration, adverse drug reaction (ADR), and documentation.

Pre- and post-prospective review data was to be analyzed in order to compare rate of appropriateness based on established monitoring parameters developed for specified medications. This information would then be used to identify estimated cost avoidance (ECA) to the health system based on accepted pharmacist interventions. ECA was internally developed based on published literature focusing on both inpatient and outpatient metrics[14-15]. The level of the intervention outcome and corresponding estimated cost avoidance is outlined in Table 1.

Table 1: Intervention Outcome Classification

Outcome Level	Description	Estimated Cost Avoidance ($)	Frequency	Total ECA ($)
Level 1	Improved Quality of Care	0	18	0
Level 2	Avoided drug product costs	calculated based on drug product savings	0	0
Level 3	Avoided additional physician visit	366.73	4	1,466.92
Level 4	Avoided additional prescription order	424.33	4	1,697.32
Level 5	Avoided emergency room visit	845.25	0	0
Level 6	Avoided hospital admission	26,205.40	0	0
				3,164.00

Results

A 2013 usage report run for medications administered in the infusion center revealed 9,934 medications during the time period. Table 2 outlines the top ten medications administered based on usage (hydration and pre-medications were excluded from the usage report e.g. intravenous fluids, acetaminophen). The top five medications (methylprednisolone, infliximab, immune globulin, methotrexate, omalizumab) were shown to make up 60% of total doses administered within the

infusion center. Of those five medications, all but methylprednisolone contained an FDA boxed warning regarding its use. With this information at hand, the following medications were chosen to have specific monitoring parameters developed for their safe use within the infusion clinic: methylprednisolone, infliximab, immune globulin, methotrexate, omalizumab.

Table 2: Infusion Center Medication Usage (1-year)

Medication	Number of doses administered	Percentage of total number of drugs administered (%)
Methylprednisolone	2583	26
Infliximab	1842	19
Immune Globulin	855	9
Methotrexate	552	6
Omalizumab	521	5
Ondansetron	434	4
Cosyntropin	219	2
Epoetin Alfa	129	1
Mesna	117	1
Tocilizumab	70	<1

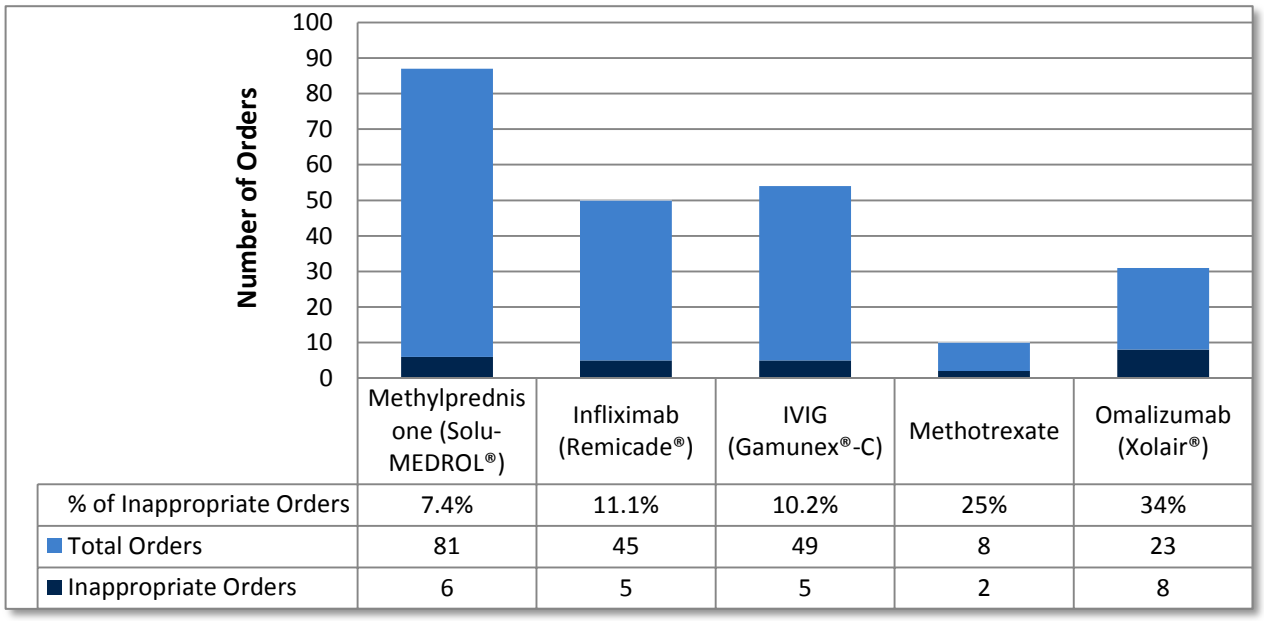
The following monitoring parameters were developed for the chosen medications:

- Methylprednisolone: baseline vitals recorded, glucose screening, indication, dose appropriate, infusion time, frequency of therapy
- Infliximab: Tb screening documented, baseline vitals recorded, indication, dose appropriate based on indication, infusion time (>2 hours), CBC/CRP/LFTs, frequency of therapy
- Immune globulin: baseline vitals recorded, indication, dose appropriate, infusion time, IgG level (date), CBC, frequency of therapy
- Methotrexate: current antibiotic therapy pregnancy test on file, indication, dose appropriate, leucovorin/folate therapy, CBC/LFTs
- Omalizumab: presence of epinephrine IM auto-injector with patient, inclusion criteria met, IgE level (date), indication, dose appropriate, post-infusion anaphylactic monitoring

The second objective of creating and implementing a tool to evaluate appropriateness of orders (laboratory monitoring, dose, duration of therapy, post-infusion monitoring) was accomplished by utilizing electronic medical records to review therapy plans entered by physicians for individual patients. Due to the nature of when therapy plans were entered by physicians, many therapy plans were not entered 7 days before the patient was scheduled for their appointment. For this reason, the decision was made to implement a 4-day prospective patient review in order to properly capture the therapy plans for patients. The clinic pharmacist reviewed therapy plans for patients scheduled for appointments 4 days in advance to allow proper time for interventions to be made as necessary.

In regards to the objective of identifying financial risk and benefit for the organization through an increased pharmacy presence in a high-risk, high-cost ambulatory setting, the following results were obtained. From January 6, 2014 – February 7, 2014 there were 206 infusions of one of the five medications identified for monitoring. Of those, 26 were deemed to be inappropriate and resulted in pharmacist interventions, representing an inappropriate order rate of 12.6%. Figure 1 shows the number of inappropriate order based on drug and as a percentage of total orders.

Figure 1: January Medication Infusions

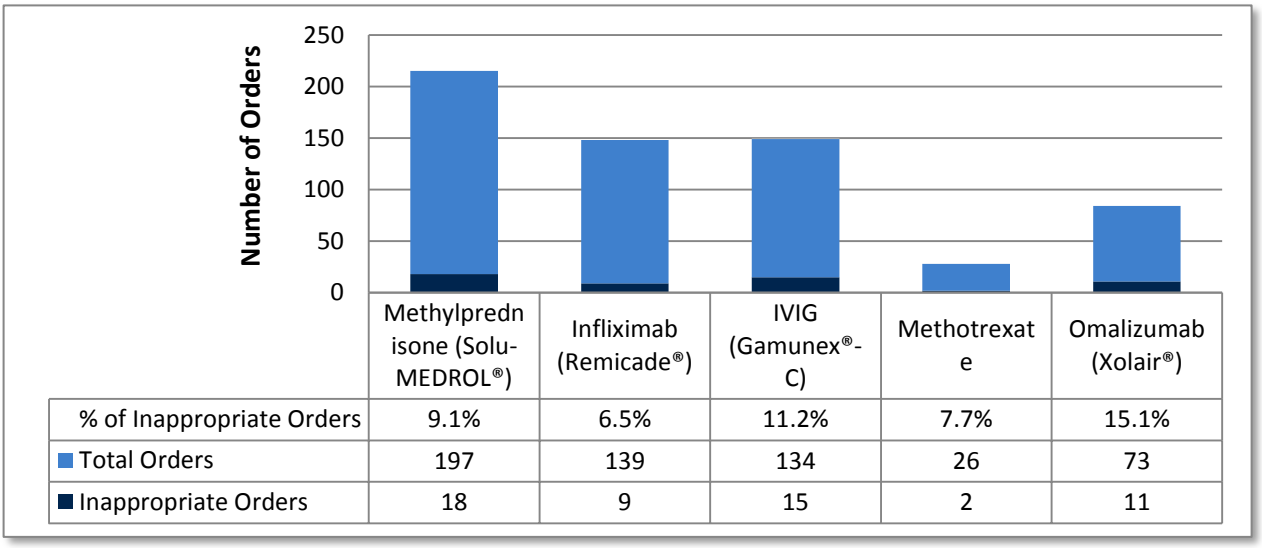


	Methylprednisone (Solu-MEDROL®)	Infliximab (Remicade®)	IVIG (Gamunex®-C)	Methotrexate	Omalizumab (Xolair®)
% of Inappropriate Orders	7.4%	11.1%	10.2%	25%	34%
Total Orders	81	45	49	8	23
Inappropriate Orders	6	5	5	2	8

Retrospective review of the five medications administered during the period of September 15, 2013 – December 15, 2013 revealed there were 569 administrations with 55 instances of inappropriate

orders that would have warranted a pharmacist intervention. This represented an inappropriate order rate of 9.6% (Figure 2).

Figure 2: September - December Medication Infusions



Inappropriate orders identified in the month of January were classified into one of the following five categories: labs, dosage, duration, adverse drug reaction, documentation. Table 3 outlines the errors classified by type for each individual drug.

Table 3: Classification of Inappropriate Orders

	Methylprednisolone	Infliximab	Immune Globulin	Methotrexate	Omalizumab	Total	% of Total
Labs	3	2	4	0	3	12	46.2%
Dosage	0	0	1	0	1	2	7.7%
Duration	2	1	0	0	0	3	11.5%
Adverse Drug Reaction	0	0	0	0	3	3	11.5%
Documentation	1	2	0	2	1	6	23.1%
Total (%)	6 (23)	5 (19.2)	5 (19.2)	2 (7.7%)	8 (30.8)	26	

This information was applied to an established estimated cost avoidance (ECA) tool that was classified into progressively more severe outcomes. Eighteen interventions made were level 1 outcomes, which do not directly result in cost avoidance. Four interventions were classified as level 3 outcomes, which result in the avoidance of an additional physician visit. Interventions for level 3 outcomes involved the ordering of labs based on pertinent patient history, and documentation. There were four level 4 outcomes, which result in the avoidance of additional prescription orders. These interventions involved adverse drug reaction precautions and drug preparation. In total, results showed an overall estimated cost avoidance due to interventions made to be $3,164 (Table 4).

Table 4: Estimated Cost Avoidance (ECA) by Intervention

Outcome Level	Description	Estimated Cost Avoidance ($)	Frequency	Total ECA ($)
Level 1	Improved Quality of Care	0	18	0
Level 2	Avoided drug product costs	calculated based on drug product savings	0	0
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3,164.00				

Discussion

This study evaluated the impact of a pharmacist integrated into a pediatric infusion center on estimated cost avoidance while also outlining the steps towards implementing the tools for the pharmacists to utilize for prospective review of infused high-risk meds. The results showed that out of 36 total interventions made, 18 led to avoiding an estimated cost of $3,164. Additionally, when comparing interventions made during the 1-month intervention period with a 3-month retrospective review of patient therapy plans, it was shown that the rate of inappropriate orders were shown to have similar rates (12.6% vs. 9.6%) of inappropriate orders. The results showed that a pharmacist's interventions resulted in $3,164 of estimated cost avoidance. This monetary figure was a result of

eight interventions made that according to an established cost avoidance tool saved the institution as well as the patient money. The other 18 interventions could not be correlated to monetary savings; however their presence did improve the quality of the care for the patient.

The development of standardized monitoring parameters for the five drugs making up 60% of usage over one year will help to improve efficiency within the pharmacy from an order verification perspective. This will also help to establish a stronger relationship between pharmacy and the medical team, as these parameters will enable the pharmacist to feel confident in alerting physicians to interventions. Literature devoted to establishing a culture of safety has identified reluctance to call a colleague to question an order or ask for more information due to fear of disrespectful behavior as a barrier to safety[16-17]. When communication between health care team members is limited, the patient is often the one who suffers.

The use of technology in the expansion of pharmacy services in the ambulatory clinic was crucial in this study, as therapy plans were able to be viewed by pharmacists before orders were released for the patient arrived for the appointment. As discussed, the therapy plans include all information and directives related to the patient's scheduled visit entered by the physician. This includes information related to physical assessments, labs to be drawn, infusion times, dose, pre-medications, hydration, and post-infusion monitoring directives. While this information was available to pharmacists in the past, it was located in different areas of the patient electronic health record. This was a cumbersome and time-intensive process to locate all of this information from the pharmacist's perspective along with handling other assigned duties within the pharmacy satellite. From a time management perspective, waiting until the order was "released" the day of the appointment was more efficient from the pharmacist's perspective. Gaining access to therapy plans allows for pharmacists to have all pertinent information relating to the patient appointment in one place and better facilitates a true prospective review.

Limitations to this study include a short-term intervention period, lack of well-defined cost avoidance tool, documentation variation, and lack of historical potential adverse drug event (pADE) data to use as a baseline. Future studies should focus on the development of an ambulatory care cost avoidance tool that can be utilized to tangibly realize the impact of services, technology, or processes. There is a

paucity of literature devoted to the benefit to pharmacists on safety and quality in ambulatory settings, particularly in the pediatric setting. With the growing emphasis being placed on transitions of care, literature devoted to exploring the pharmacist's role in that transition would be welcomed.

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